

REMARKS

Prior to the present amendment, claims 1-25 were pending. Claims 8, 12 and 25 are withdrawn from consideration as reciting a non-elected invention. In the present amendment, claims 13, 14, 16 and 20 have been cancelled. Accordingly, claims 1-7, 9-11, 15, 17-19 and 21-24 are currently pending.

In the Office Action, claims 13, 14 16 and 20 were rejected under 35 U.S.C. §112, first paragraph allegedly for lack of enablement. Applicants have cancelled claims 13, 14, 16 and 20. Accordingly, the rejection is now moot and should be withdrawn. Applicants preserve the right to pursue the subject matter to claims 13, 14 16 and 20 in continuing applications.

Claims 1-7, 9-10, 13-17, 19-24 were rejected under 35 U.S.C. §103(a) for allegedly being obvious over Stuhler et al., Sastry et al. and Sugimoto et al. Applicants respectfully disagree that the claimed invention is obvious.

Stuhler et al. discloses *in vitro* induction of cytolytic T lymphocytes by incubating HLA-A2 positive peripheral blood mononuclear cells with a combination of a helper T cell epitope and a CTL epitope. At most, Stuhler et al. teaches that CTL and helper T antigens are required to elicit a cytotoxic T-cell response (see abstract). The claimed invention discloses micelle compositions comprising CTL antigenic determinants and helper T antigenic determinants. However, there is no disclosure in Stuhler et al. of micelle compositions containing CTL and helper T antigens.

Sastry et al. discloses induction of a cytolytic immune response against HIV without the simultaneous induction of an antiviral antibody response (see abstract). Sastry et al. further discloses micelle compositions containing a peptide sequence (Peptide Polymer section on page 700 of Sastry et al.).

Sugimoto et al. reports the adjuvant effect of a synthetic peptidoglycan (see abstract).

As emphasized and discussed in detail in the previous amendment dated April 1, 2004, nowhere in Stuhler et al., Sastry et al. or Sugimoto et al. is there any disclosure or suggestion of the essential technical feature of the claimed invention. See pages 11-12 of the amendment dated April 1, 2004.

Specifically, nowhere in the cited references is there any disclosure or suggestion of a composition comprising **more than one first lipopeptide** comprising at least one CTL antigenic determinant and at least one lipid unit, and a second lipopeptide comprising at least one T helper determinant and at least one lipid unit.

The examiner indicates that the applicants' arguments presented in the Amendment dated April 1, 2004 were unpersuasive. The examiner alleges that contrary to applicants' assertions, Sastry et al. does teach administering more than one first lipopeptide comprising at least one CTL antigenic determinant and at least one lipid unit. The examiner cites the abstract and the section titled "Peptide Polymers" on page 700 of Sastry et al.

According to the examiner, the abstract and "Peptide Polymers" section disclose eliciting cell-mediated immunity with micelles comprising short HIV envelope peptides of gp160 with two palmitic residues attached to the amino-terminal lysine. The examiner further contends that Sastry et al. discloses generation of the micelle compositions by dissolving the peptides with the palmitic residues attached in acetic acid. Thus, the examiner concludes that Sastry et al. teaches a composition comprising more than one first lipopeptide comprising at least one CTL antigenic determinant and at least one lipid unit.

Applicants respectfully disagree with the examiner. Nowhere in Sastry et al. is there any disclosure or suggestion of a composition comprising micelles wherein each micelle contains more than one first lipopeptide comprising at least one CTL antigenic determinant and at least

one lipid unit and a second lipopeptide comprising at least one T helper determinant and at least one lipid unit.

The Sastry et al. abstract merely discloses that micelles containing short peptide sequences of HIV gp160 were generated. The procedure for generating the micelles is disclosed in the "Peptide Polymers" section on page 700 of Sastry et al., which states the following:

...Two types of polymers were prepared: ... (2) lipid micelle polymers formed by attaching an amino-terminal lysine to the **peptide sequence in question** and then coupling a fatty acid to both the alpha and epsilon amino groups...*(Emphasis Added)*

The emphasized words "peptide sequence in question" suggests that the micelles contain one peptide sequence. Thus, Sastry et al. discloses that each micelle **do not contain more than one first lipopeptide and a second lipopeptide**, as is required in the claimed invention.

This deficiency of Sastry et al. is further supported in the first full paragraph on page 702, which states that following:

Synthetic peptides selected from the three functionally important regions described above were tested in both the disulfide polymeric (peptides 61, 63, 65 and 67) and palmitic acid micellar (peptides 62, 64, 66 and 68) forms. ...**Each of these peptides in the micellar form** also induced anti-peptide antibodies at levels similar to respective disulfide forms. *(Emphasis added)*

Again, the emphasized phrase "each of these peptides in the micellar form" indicates only one peptide sequence. Accordingly, a person having ordinary skill would not perceive that the micelles of Sastry et al. contain more than one first lipopeptide and a second lipopeptide.

Further, Sastry et al. teaches the induction of a cytolytic response against HIV **without** the simultaneous induction of an antiviral antibody response (see page 700, first column, beginning at line 2). To achieve this purpose, Sastry et al. administered a single peptide to mice in order to distinguish those peptides which only elicit a cytolytic response without the simultaneous induction of an antiviral antibody response.

Thus, taken into account the unique goal of Sastry et al. of selecting precisely each pertinent peptide, Sastry et al. clearly dissuades one skill in the art to use peptide preparations containing a mixture of peptides.

In contrast, the claimed invention requires a mixture of peptides (i.e., more than one first lipopeptide comprising at least one CTL determinant and at least one lipid unit and a second lipopeptide comprising at least one Helper T antigenic determinant and at least one lipid unit). Therefore, Sastry et al. teaches away from the claimed invention.

For all the reasons given above, claims 1-7, 9-10, 13-17, 19-24 are not obvious over Stuhler et al., Sastry et al. and Sugimoto et al. Applicants respectfully request that the rejection the claims under §103(a) be reconsidered and withdrawn.

Claim 11 was rejected under 35 U.S.C. §103(a) for allegedly being obvious over Stuhler et al. and Sastry et al. and Sugimoto et al., and further in view of Kramer et al. The examiner points to the Kramer et al. reference for the disclosure of the GAG 253 peptide as an immunogenic sequence, and of its use in detection assays and pharmaceutical compositions.

Applicants note that claim 11 is dependent on independent claim 1. Applicants have provided arguments to refute the rejection of claim 1 over Stuhler et al., Sastry et al., and Sugimoto et al. (see above). Accordingly, claim 11 is patentable at least for the same reasons that claim 1 is patentable.

Therefore, applicants respectfully request that the rejection of claim 11 under §103(a) be reconsidered and withdrawn.

Claim 18 was rejected under 35 U.S.C. §103(a) as allegedly obvious over Stuhler et al., Sastry et al., Sugimoto et al. and Kramer et al. and further in view of Shapiro et al. The

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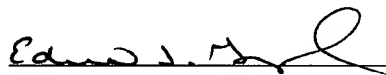
examiner cites the Shapiro et al. reference for teaching the use of two-dimensional magnetic resonance to aid in analyzing the conformation of micelle/peptide-receptor interactions.

As discussed at length above, the combination of Stuhler et al., Sastry et al., Sugimoto et al. and Kramer et al. does not lead to the claimed composition comprising. The addition of the teachings of Sharipo et al. concerning the use of two-dimensional NMR fails to repair this defect.

Accordingly, applicants respectfully request that the rejection under §103 be reconsidered and withdrawn.

For all of the above reasons, applicants respectfully request allowance of the pending claims. If the examiner has any questions regarding this amendment, the examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,



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